

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD.,
Plaintiff,

v.

SAREPTA THERAPEUTICS, INC.,
Defendant.

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)
) C.A. No. 21-1015 (GBW)

)
) **DEMAND FOR JURY TRIAL**
)

SAREPTA THERAPEUTICS, INC. and THE
UNIVERSITY OF WESTERN AUSTRALIA,
Defendant/Counter-Plaintiffs

v.

NIPPON SHINYAKU CO., LTD. And NS
PHARMA, INC.,
Plaintiff/Counter Defendants.

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**PLAINTIFF'S MEMORANDUM OF LAW IN SUPPORT OF ITS *DAUBERT* MOTION
TO EXCLUDE TESTIMONY AND OPINIONS OF ANDREW HIRSHFELD**

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Dated: December 11, 2023

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I INTRODUCTION

Defendant Sarepta Therapeutics, Inc.’s (“Sarepta”) expert, Andrew Hirshfeld, offered multiple improper legal opinions. His October 11, 2023 Expert Report (“Opening Report”) is littered with rote recitation of patent law and portions of his October 27, 2023 Rebuttal Report (“Rebuttal Report”) read like a motion *in limine* legal brief as opposed to helpful expert opinion. Such opinions reciting legal standards with the gloss of purportedly “expert” testimony have repeatedly been excluded in this District and by this Court. The result should be the same here.

II SUMMARY OF THE ARGUMENT

Mr. Hirshfeld should not be permitted to offer legal opinions regarding governing law on issues of patentability, inequitable conduct, and the duty of candor. Permitting him to do so “would usurp the District Court’s pivotal role in explaining the law to the jury.” *Berkeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 217 (3d Cir. 2006) (internal citations omitted). The impropriety of expert legal opinion like that Mr. Hirshfeld purports to offer is well-established in this District. *See, e.g., PureWick Corp. v. Sage Prod., LLC*, No. CV 19-1508 (MN), 2021 WL 2593338, at *1, *2 n.3 (D. Del. June 24, 2021); *Persawvere, Inc. v. Milwaukee Elec. Tool Co.*, C.A. No. 21-400-GBW, 2023 WL 8019085, at *15 (D. Del. Nov. 20, 2023) (noting “well-established practice” of exclusion of “legal experts”).

III STATEMENT OF FACTS

Sarepta retained an attorney expert to provide opinions regarding the subject of “patent practice and procedures generally, and specifically as they relate to” Sarepta’s asserted patents in this case. *See* Ex. 8 (Expert Report of Andrew H. Hirshfeld (“Hirshfeld Opening”)), ¶ 1. But in reality Sarepta’s expert, Mr. Hirshfeld, offers lengthy recitations of the law (including extensive case citations) pertaining to, *inter alia*, written description, enablement, inventorship, duty of candor, and inequitable conduct. *See id.*, ¶¶ 23-31, 69-75, 86-100. Indeed, in his rebuttal report, Mr. Hirshfeld

goes so far as to offer his “belief” of whether another one of Sarepta’s expert’s opinions are “consistent with expectations of an expert witness” based on case law from this District. *See* Ex. 9 (Expert Rebuttal Report of Andrew H. Hirshfeld (“Hirshfeld Rebuttal”)) ¶¶ 12-14.

IV ARGUMENT

Mr. Hirshfeld’s legal opinions and speculation flowing therefrom would be wholly impermissible if offered to a jury and such opinions are likewise unhelpful to the Court for issues such as inequitable conduct, enablement, and written description—legal issues with which the Court is well familiar. Recognizing the impropriety of a purported expert telling the Court or the jury what the law is, courts in this District “ha[ve] a well-established practice of excluding the testimony of legal experts, absent extraordinary circumstances.” *AstraZeneca UK Ltd. v. Watson Lab’ys, Inc. (NV)*, No. 10-915-LPS, 2012 WL 6043266, at *1-2 (D. Del. Nov. 14, 2012) (collecting cases and excluding patent law expert testimony, including on procedures at the PTO) (internal citations omitted); *Berkeley*, 455 F.3d at 217.

Indeed, “[t]he law of this [D]istrict is clear that experts in patent cases may not opine on whether a party engaged in inequitable conduct, discuss whether certain information was material to a pending patent application, or otherwise provide legal conclusions on ‘substantive issues of patent law.’” *Brigham & Women’s Hosp. Inc. v. Teva Pharms. USA, Inc.*, No. 08-464, 2010 WL 3907490, at *2 (D. Del. Sept. 21, 2010) (citing cases); *Shire Viropharma Inc. v. CSL Behring LLC*, No. 17-414, 2021 WL 1227097, at *16-17 (D. Del. Mar. 31, 2021) (excluding legal analysis and legal opinion testimony regarding inequitable conduct). The reason for this is simple: “descriptions of the law and instructions on the law are matters for the court” and any “such testimony frequently amounts to the proffering of impermissible legal opinions.” *AstraZeneca*, 2012 WL 6043266, at *1 (citations omitted); *Shire Viropharma*, 2021 WL 1227097, at *16-17; *Lannett Co. Inc. v. KV Pharm., Drugtech Corp.*, No. 08-338-JJF, 2009 WL 10657988, at *4-5 (D. Del. Mar. 9, 2009) (excluding legal

expert opinions as improper attempt “to offer testimony on the ultimate legal issue in the case”—patent unenforceability due to inequitable conduct—“usurp[ing] the role of [] judge”). Mr. Hirshfeld’s opinions mirror those that these other courts have excluded.

Here, Sarepta purports to have Mr. Hirshfeld tell the Court and/or jury—under the gloss of supposed “expert” testimony—what the governing law is regarding written description, enablement, inventorship, duty of candor, and inequitable conduct. *See* Ex. 8 (Hirshfeld Opening) ¶¶ 23-31, 69-75, 86-100. He also purports to instruct this Court (or the jury) regarding what another expert is permitted to testify—plainly something an expert witness is not allowed to do. *See* Ex. 9 (Hirshfeld Rebuttal) ¶¶ 12-14. These paragraphs of Mr. Hirshfeld’s reports are infused with citations to statutes, regulations, and legal precedent—a far cry from a mere overview of “internal PTO practices and procedures.” *Shire Viropharma*, 2021 WL 1227097, at *16 (excluding impermissible legal expert opinion that was framed as opinion regarding “internal PTO practices and procedures”).

This Court recently rejected efforts to do precisely what Mr. Hirshfeld purports to do in this case: improperly attempt to instruct the Court and/or jury on the law. *See Persawvere, Inc.*, 2023 WL 8019085, at *15 (D. Del. Nov. 20, 2023) (rejecting purported patent law expert’s effort to instruct the fact-finder on law of inequitable conduct as “not helpful”). The result should be the same here.

Dated: December 11, 2023

Respectfully submitted,

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